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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/911,874	07/24/2001	Stuart D. Edwards	9222.16792	4783

26308 7590 10/01/2002

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EXAMINER	
PEFFLEY, MICHAEL F	
ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 10/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/911,874	Applicant(s) EDWARDS ET AL.	
	Examiner Michael Peffley	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (f) he did not himself invent the subject matter sought to be patented.

Claims 1, 5, 7-19, 21, 22, 24, 27-37, 45-52, 54, 55, 57, 60-68, 78-80 and 82 are rejected under 35 U.S.C. 102(b) as being anticipated by Avitall ('493).

Avitall discloses a device which comprises an introducer (18), an expandable device means coupled to the introducer and having first and second arms (28,30) which are expandable to a deployed state. A plurality of mapping/treatment electrodes is located on the expandable member for the treatment of tissue. While Avitall does not specifically disclose the use of the device to treat a sphincter, the examiner maintains that the structure is identical to that set forth in the claims and that the device is inherently capable of performing such a procedure.

Claims1-43, 45-47, 50-76 and 78-82 are rejected under 35 U.S.C. 102(e) as being anticipated by Edwards ('730).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the

reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Edwards discloses a device which includes an expandable member (32) having deployed and non-deployed states. An energy delivery device (i.e. RF electrodes, microwave antenna, fiber optics, etc – col. 7, lines 33+) is coupled to the expandable member, and a flexible coupling member (14) is also coupled to the expandable member. There is no disclosure that the device is used to treat a sphincter; however the examiner maintains that the structure is inherently capable of performing such a procedure and applicant's recitation of intended use bears no patentable weight to the claims. The energy delivery device may include a flexible electrical circuit (Figure 3), and the expandable member is porous for the delivery of a fluid to tissue.

Claims 1-82 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. This application is a continuation of US Serial No. 09/007,237. The claims in the instant application are essentially identical to those that were presented in the '237 application. However, the '237 application contained only Stuart D. Edwards as the inventor. The instant application now cites Stuart D. Edwards and David S. Utley as co-inventors which contradicts the inventorship as originally filed in the '237 application. There is no evidence of a petition to change inventorship, and applicant's transmittal indicates that the instant application has the same inventorship as the parent application (which is incorrect). Also note that the anticipation of the claim

language by the Edwards ('730) patent appears to make evident that Stuart D. Edwards was the sole inventor of the subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 47-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards ('730) in view of the teaching of Edwards et al ('672).

Edwards ('730) fails to specifically disclose a mechanical expansion means and a viewing means (i.e. fiber optics) for viewing tissue.

The Edwards et al ('672) system is substantially identical to the ('730) system, but further teaches of the use of a mechanical expansion means (Figure 4A) as well as the use of fiber optics for viewing tissue (Figure 3 – col. 6, lines 28+).

To have provided the Edwards ('730) system with a mechanical means to expand the balloon and a visualization system to view tissue would have been an obvious consideration for one of ordinary skill in the art in view of the teaching of Edwards et al ('672).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-82 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-88 of U.S. Patent No. 6,056,744. Although the conflicting claims are not identical, they are not patentably distinct from each other because the use of the arms having sufficient spring force to dilate a sphincter as the expandable member is deemed to be obvious design considerations and/or inherent properties of the system.

Claims 1-82 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-51 of U.S. Patent No. 6,254,598. Although the conflicting claims are not identical, they are not patentably distinct from each other because the use of the arms having sufficient spring force to dilate a sphincter as the expandable member is deemed to be obvious design considerations and/or inherent properties of the system.

Terminal Disclaimer

The Terminal Disclaimer filed July 24, 2001 is unacceptable because:

1) the disclaimer fee of $55 in accordance with 37 CFR 1.20(d) has not been submitted, nor is there any authorization in the application file to charge a specified Deposit Account or credit card.

2) The application/patent which forms the basis for the double patenting rejection is not identified in the terminal disclaimer.

It is noted that the Disclaimer attempts to disclaim US Serial No. 09/007,283 filed on January 14, 1998, which application is currently abandoned.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (703) 308-4305. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Michael Peffley
Primary Examiner
Art Unit 3739

mp
September 26, 2002